

REMARKS:

This is in response to the Final Office Action mailed July 17, 2007. Claims 15, 16, 17, 19, 40 and 41 have been cancelled. Claim 34 has been amended to better describe the invention and all claims have been made to depend either directly or indirectly from claim 34. That is , all claims have been amended to recite a method for treating schizophrenia using a pharmaceutical composition comprising particular extracts as claimed. In addition, changes to the claims have been made in order to address the objections and 35 U.S.C. §112 issues in the Final Office Action so as to place the claims in condition for allowance. No new matter has been added.

With respect to the objection of the term “*ginesoids*” made by the Examiner, it is respectfully asserted that the term is correct as used for the following reasons. The term “*ginsenoids*” is well defined in the scientific community and in the present application in original claim 8. That is, “*ginsenoids*” are glycosides of triterpenes and are defined in original claim 8 as belonging to the group of triterpene saponines.

As for the objection of claim 20 wherein it is stated that it is not clear how saffron and safranal are related. Claim 20 has been amended to better clarify that safranal is a degradation product of saffron via an intermediate of picrocrocin. Therefore, it is respectfully submitted that safranal as used in the claims is fully supported and described by the specification including claim 20 as amended. In view of the foregoing amendments to the claims and the remarks herein above, it is respectfully requested that the objections of claims 14-16, 18-25, 29, 30 and 34 -41 be reconsidered and withdrawn.

In the Office Action, claims 14-16, 18-25, 29, 30 and 34-41 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Applicants respectfully disagree and it is respectfully asserted that the claims, as amended, provide a clear teaching of what the pharmaceutical composition of the present invention comprises. This teaching, as well as, the discussion of a full working example on pages 9 to 11 of the English translation of the International Application which discusses the pharmaceutical effectiveness of the present invention, fully enables the present invention. That is, given the relatively high level of skill of one skilled in the art, the clear claim language as amended and the teaching on how to realize the present invention discussed above, it is respectfully submitted that the claims as amended are fully enabled by the instant specification. Accordingly, it is respectfully requested that the rejection of claims 14-16, 18-25, 29, 30 and 34 - 41 under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

In the Office Action, claim 21 has been rejected under 35 U.S.C. § 112, first paragraph, for allegedly not containing a written description of the subject matter claimed. In particular, the Examiner alleges that the Applicants fail to describe what is meant by the term "*ginsenoids*" and that the Applicants were in possession of the genus of what constitute "*gensenoids*" at the time of filing. As set forth above in the objection of the use of *gensenoids* in the claims, *gensenoids* are well known as glycosides of triterpenes and are defined in original claim 8 as belonging to the group of triterpene saponines. Therefore, one skilled in the art would recognize that the applicants were in possession of the genus of what constitutes *gensenoids* and

therefore the Applicants respectfully request that the rejection of claim 21 be reconsidered and withdrawn.

In the Office Action, claims 15, 16, 18-24, 29, 30 and 39-41 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter claimed. In making the rejection the Examiner stated that “the metes and bounds of Claim 15 are uncertain because of the use of the whole plant and plant parts in a medicament. Claim 15 has been cancelled and all claims now depend on claim 34 as amended. Claim 34 and the remaining claims are directed to a method of treating schizophrenia using a pharmaceutical composition comprising extracts of particular plants. Using extracts of plants in general is a practice well known in the pharmaceutical field and the use of extracts of the recited plants in general would not be indefinite to one skilled in the art. Therefore, the rejection of claims 15, 16, 18-24, 29, 30 and 39-41 as being indefinite must be reconsidered and withdrawn.

Turning now to the rejection of the Claims on the merits. Claims 14-16, 18, 22-24, 29, 30, 40 and 41 have been under 35 U.S.C. § 102(a) as allegedly being anticipated by Bombardelli et al. (US PreGrant Publication; 2001/0000326 A1). For the reasons stated below the Applicants assert that Bombardelli does not teach or suggest the subject matter of the claims as amended.

Bombardelli et al. teaches a method for extracting *Hypericum perforatum* by fractioning specific extracts of the plant with esters of water-immiscible C₁ to C₅ alcohols. In contrast to the present invention, *Bombardelli et al.* only refers to a treatment of depression and anxiety, which has, however, very little if anything in

common with the disease of schizophrenia. This is discussed in the English translation of the international application of the present invention. The application explicitly states that schizophrenia is delimited over depression by means of its symptoms. That is, the symptoms of schizophrenia are delimited over depression since in schizophrenia there is a lack of a prominent depressed mood, as well as, schizophrenia having different temporal progression of disorders than depression (paragraph bridging page 1 and 2 and paragraph bridging page 3 and 4 of the English translation of the PCT filing text). The fact that depression can be markedly distinguished from schizophrenia can also be seen on the basis of the internationally valid classification scheme ICD10 (International Classification of Mental Disorders, 10th edition, published by the World Health Organization) according to which schizophrenia can be clearly delimited over depression. Therefore, Bombardelli et al. fails to teach or suggest a method for treating schizophrenia as recited in the claims as amended. Accordingly, it is respectfully requested that the rejection of claims 14-16, 18, 22-24, 29, 30, 40 and 41 under 35 U.S.C. § 102(a) in view of Bombardelli et al. be reconsidered and withdrawn.

In the Office Action, claims 14-16, 19, 21, 22, 24, 40 and 41 have been rejected under 35 U.S.C. §102(a) as allegedly being anticipated by Petrini et al. (US Publication: 2002/0015744 A1). Petrini et al. refers to a dietary supplement consisting of a combination of ginseng and ginkgo to improve the speed of memory and memory quality in **normal healthy subjects** and to prevent deterioration of the speed of memory in people with decreased cognitive functions and **not** for the treatment of schizophrenia. In fact, Petrini et al. is completely silent with respect to schizophrenia.

Moreover, Petrini et al. does not teach or suggest the use of a composition comprising *Hypericum perforatum* for any treatment, let alone for the treatment of schizophrenia. Accordingly, Petrini et al., does not teach or suggest the claimed subject matter as amended. In view of the foregoing, it is respectfully requested that the rejection of claims 14-16, 19, 21, 22, 24, 40 and 41 under 35 U.S.C. §102(a) in view of Petrini et al. be reconsidered and withdrawn.

In the Office Action, claims 14-16, 19, 22, 40 and 41 have been rejected under 35 U.S.C. §102(a) as being anticipated by Schwabe (US Patent Number 5,322,688). A review of the *Schwabe* reference clearly indicates that the reference refers to a method of preparation of an improved extract from *Ginkgo biloba* leaves and to pharmaceuticals containing extracts of the same. However, Schwabe fails to teach or suggest a method for the treatment of schizophrenia using a composition comprising *Hypericum perforatum* as recited in the claims as amended. That is, the claims, as amended, are directed to a method for treating schizophrenia using a composition that does not contain *Ginkgo biloba* leaves but instead contains an extract of *Hypericum perforatum*. As stated above, Schwabe is silent on using a composition comprising *Hypericum perforatum* for any use let alone for the treatment of schizophrenia. Therefore, Schwabe fails to teach or suggest a method for treating schizophrenia using a composition comprising *Hypericum perforatum* as recited in the claims as amended. For this reason, it is respectfully requested that the rejection of claims 14-16, 19, 22, 40 and 41 under 35 U.S.C. §102(a) in view of Schwabe be reconsidered and withdrawn.

In the Office Action, claims 14-16, 22, 24, 40 and 41 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Mori et al. (N. JP 11-080009 A). JP'009 teaches a medicine comprising saffron powder an extract of saffron and ginkgo extract to treat brain functions without side effects. However, JP '009 does not teach or suggest a composition comprising *Hypericum perforatum* for the treatment of schizophrenia as recited in the claims as amended. As it is well known that in order to maintain a rejection under 35 U.S.C. 102(b) a single reference must teach each and every element of the invention as they are arranged in the claims, JP'009 does not teach a method for treating schizophrenia using a composition comprising *Hypericum perforatum*. This is acknowledged by the Examiner in making the rejection at page 22 of the Final Office Action. Here, the Examiner clearly acknowledges that it "is noted that the reference (JP '009) does not teach that the composition can be used in the manner instantly claimed..." Moreover, the claims as amended are even further removed from JP '009 in that JP '009 fails to teach or suggest a composition comprising *Hypericum perforatum*. Therefore, in view of the foregoing it is respectfully requested that the rejection of claims 14-16, 22, 24, 40 and 41 under 35 U.S.C. § 102(b) in view of JP '009 be reconsidered and withdrawn.

In the Office Action, claim 29 has been rejected under 35 U.S.C. § 102(b) as being anticipated by Zhang et al. (A Double-Blind, Placebo-Controlled Trial of Extract of Ginkgo biloba added to Haloperidol in Treatment-Resistant Patients with Schizophrenia. Journal of Clinical Psychiatry, vol. 62, No. 11 (November 2001), pp. 878-883). A close review of Zhang et al indicates that this reference refers to the

treatment of treatment-resistant patients with schizophrenia using extracts of *Ginkgo biloba* plus haloperidol. This reference is silent with respect to treating schizophrenia in general with a composition comprising extracts from *Hypericum perforatum*, *Crocus sativus* and *Panax ginseng* either individually or in combination. In fact, Zhang does even mention a composition comprising extracts from *Hypericum perforatum*, *Crocus sativus* and/or *Panax ginseng* for the treatment any disease let alone for the treatment of schizophrenia as recited in the claims as amended.

Accordingly, it is respectfully requested that the rejection of claim 29 under 35 U.S.C. § 102(b) in view of Zhang et al. be reconsidered and withdrawn.

Finally, the Examiner has rejected claims 34-37 and 39 under 35 U.S.C. § 103(a) as being unpatentable over Zhang et al in view of Petrini et al. As stated above, Zhang refers to the treatment of treatment-resistant patients with schizophrenia using extracts of *Ginkgo biloba* plus haloperidol. This reference is silent with respect to treating schizophrenia with a composition comprising extracts from *Hypericum perforatum*, *Crocus sativus* and *Panax ginseng* either individually or in combination. In fact, Zhang does even mention a composition comprising extracts from *Hypericum perforatum*, *Crocus sativus* and/or *Panax ginseng* for the treatment of schizophrenia as recited in the claims as amended.

This factual defect is not corrected by Petrini et al since as stated above, Petrini et al. refers to a dietary supplement consisting of a combination of *ginseng* and *ginkgo* and does not teach or suggest the use of a composition comprising *Hypericum perforatum* for any treatment, let alone for the treatment of schizophrenia. Therefore,

since neither Zhang nor Petrini teach or suggest a method for treating schizophrenia comprising the administration of composition comprising extracts from *Hypericum perforatum*, *Crocus sativus* and/or *Panax ginseng*, the combination falls short from teaching the present invention of the claims as amended. For this reason, it is respectfully requested that the rejection of claims 34-37 and 39 under 35 U.S.C. § 103(a) as being unpatentable over Zhang et al in view of Petrini et al. be reconsidered and withdrawn.

Please note in view of the amendments to the claims including cancellation of claims 15, 16, 17, 19, 40 and 41, all rejections as they pertain to claims 15, 16, 17, 19, 40 and 41 are now moot in view of the fact that these claims have been cancelled.

Although the Applicants are aware that the granting of the European counterpart of the U.S. patent application does not provide precedent for allowing the U.S. patent application, the Examiner is respectfully made aware that the European counterpart of the present invention, namely EP 1 487 468 B1, has been granted based on a set of claims reciting essentially identical subject matter of the claims as amended. Accordingly, in view of the foregoing amendment and accompanying remarks, it is respectfully submitted that all claims pending herein are in condition for allowance. Please contact the undersigned attorney should there be any questions.

Favorable consideration of the application as amended is respectfully requested
and early favorable action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Leo G. Lenna', is written over a horizontal line.

Leo G. Lenna
Registration No.42,796
Attorney for Applicant(s)

DILWORTH & BARRESE LLP.
333 Earle Ovington Blvd.
Uniondale, NY 11553
Telephone: (516) 228-8484
FAX: (516) 228-8516